REMARKS

Claims 1-5 and 7-29 are pending and have been rejected under 35 U.S.C. §103(a). Claims 6 and 30-64 have been withdrawn pursuant to an election under 35 U.S.C. §121. Claim 1 is amended by this response and new claims 65 and 66 are added. Applicant will address each of the Examiner's grounds for rejection below.

Claims 1-11, 13-22 and 27-29 were rejected under 35 U.S.C. §103(a) as being unpatentable over Babish, U.S. Published Application No. 2003/0054978 A1(Babish), in view of Rath, U.S. Patent No. 6,693,129 B2 (Rath).

Claims 1, 12 and 23-29 are rejected under 35 U.S.C. §103(a) as being unpatentable over Babish in view of Gonzales Bravo et al., U.S. Patent No. 6,486,205 B2 (Gonzales-Bravo).

Applicant has amended independent claim 1 to clarify that the claimed composition is a therapeutic composition that comprises a first component comprising a long-chain normal primary aliphatic alcohol, and a second component selected from the group consisting of a B_{12} Vitamin, a D Vitamin, coenzyme Q, an omega-3 fatty acid and combinations thereof, wherein the composition is for attenuating at least one factor involved in the inflammation-associated destruction of tissue associated with autoimmune disease or immuno-inflammatory disease. Applicant added new claim 65 directed to a therapeutic composition comprising a first component comprising a long-chain normal primary aliphatic alcohol, and a second component comprising a D vitamin in association with one of a B_{12} vitamin, coenzyme Q, an omega-3 fatty acid and

combinations thereof, wherein the components of the composition are present in amounts effective for attenuating at least one factor involved in the inflammation-associated destruction of tissue associated with autoimmune disease or immuno-inflammatory disease. Applicant added new claim 66 directed to a therapeutic composition comprising a first component comprising a long-chain normal primary aliphatic alcohol, and a second component comprising a D vitamin and a B_{12} vitamin in combination with at least one of coenzyme Q, an omega-3 fatty acid and combinations thereof, wherein the components of the composition are present in amounts effective for attenuating at least one factor involved in the inflammation-associated destruction of tissue associated with autoimmune diseases or immuno-inflammatory diseases. Support for the amendment and the new claims can be found throughout the specification as filed (for example at paragraphs [023], [028], [030], [043], the Examples and the claims).

In analyzing obviousness under 35 U.S.C. § 103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background, the obviousness or nonobviousness of the subject matter is determined. See MPEP § 2141. In evaluating the differences between the prior art and the claims, the claimed invention as a whole must be considered, and the prior art must be considered in its entirety, including disclosures that teach away from the claims. See MPEP § 2141.02.

The Office contends that Babish teaches compositions comprising aliphatic

alcohols and B_{12} vitamins, that Rath teaches compositions comprising D vitamins and coenzyme Q10, that Gonzales-Bravo teaches compositions comprising omega-3 fatty acids, and that it would have been obvious to one of ordinary skill in the art to combine these various ingredients in the manner claimed in the present application in order to achieve an additive effect in the treatment of hyperlipidemia. Claims 1, 65 and 66 are not obvious in view of the references cited in the Office Action for many reasons, including that the cited references are nonanalogous art, and notwithstanding, none of the cited references, alone or in combination, teach or suggest to one skilled in the art a composition comprising a long-chain normal primary aliphatic alcohol in combination with a B_{12} vitamin, a D vitamin, coenzyme Q, an omega-3 fatty acid or combinations thereof for treatment of autoimmune diseases or immuno-inflammatory diseases.

The present invention is directed toward therapeutic compositions for treating autoimmune disease and immuno-inflammatory disease. See e.g., claims 1, 65 and 66. Autoimmune disease refers to a disease of the tissues of the body caused by immuno-responsiveness against self-tissues and associated with production of inflammatory factors, which further promote tissue destruction. Autoimmune diseases include diseases such as multiple sclerosis (MS) and rheumatoid arthritis (RA). See the specification of the present application at paragraph [031]. All of the references cited by the Office are generally directed toward compositions for treating cardiovascular arterial disease (CAD) and specifically directed toward the treatment of hyperlipidemia. See the Office Action at page 4, paragraph 3 and page 6, paragraph 3. Hyperlipidemia refers to a condition where the serum lipid levels are elevated. This condition manifests as an

abnormally high concentration of fats in the blood. See Babish at paragraph [0027].

One of ordinary skill in the art would readily know that autoimmune diseases such as MS and RA are extraordinarily different than CAD and hyperlipidemia. The different mechanisms and characters of the different types of disease would suggest different modes of treatment to one of ordinary skill in the art. The cited references are neither in the field of Applicant's endeavor (i.e., treatment of autoimmune diseases or immuno-inflammatory diseases), and one of ordinary skill in the art would not consider compositions for treating CAD and hyperlipidemia to be reasonably pertinent to the treatment of autoimmune disease. Accordingly, the cited references are nonanalogous art, and therefore, are not within the scope of the prior art. See MPEP § 2141.01(a).

Notwithstanding that the cited references are nonanalogous art; one of ordinary skill in the art can not have any reasonable expectation of success in treating autoimmune diseases by combining various miscellaneous components selected from compositions for treating CAD and hyperlipidemia. Therefore, the cited references can not render claims 1, 65 and 66 obvious. See MPEP § 2143.02 (the prior art can only be modified or combined to reject claims as obvious as long as there is a reasonable expectation of success to one of ordinary skill in the art).

In evaluating the differences between the cited reference (if they were analogous art) and the claimed invention, one of ordinary skill in the art would not find the differences obvious. Specifically, the use of arbitarily combined and modified CAD and hyperlipidemia pharmacological compositions for the off-label treatment of autoimmune

disease is in direct contradiction to the accepted wisdom in the art. No individual of ordinary skill in the art would attempt to treat autoimmune disease with a random combination of ingredients arbitrarily selected from particular compositions intended to treat CAD and hyperlipidemia - completely different diseases.

In formulating a rejection under 35 U.S.C § 103(a) based upon a combination of prior art elements, it is necessary to identify the reason why a person of ordinary skill in the art would have combined the prior art elements in the manner claimed. See MEMORANDUM, From Margaret A. Focarino, Deputy Commissioner for Patent Operations, To Technology Center Directors, Subject: Supreme Court decision on KSR Int'l. Co. v. Teleflex, Inc., May 3, 2007.

Babish teaches two-component compositions, where the primary component is an arginine compound, and the secondary component is at least one of an aliphatic alcohol or a methyl donor cofactor (e.g., a B_{12} vitamin). See Babish abstract, paragraphs [0016] and [0017], examples 1-3, and claims 1, 15, and 17. Rath teaches a 37-component composition, where two of the 37 components are coenzyme Q10 and cholecalciferol (vitamin D_3). See Rath at column 3, paragraphs 6 and 8, example 1 and claim 1. Gonzales-Bravo teaches a mixture of fatty acids. See Gonzales-Bravo at column 2, lines 11-24; examples 1-9 and claims 1, 6 and 10.

The Office can not identify a reason why a person of ordinary skill in the art would take the composition of Babish, ignore the primary component arginine, and add two of the 37 components disclosed in Rath and/or the fatty acid mixture disclosed in

Gonzales-Bravo. Babish provides no teachings or suggestions that the arginine in the disclosed compositions is dispensable or interchangeable with additional components. In fact, arginine is taught as the primary component in all of the compositions disclosed. For Babish to serve as the primary reference on which to base a rejection under 35 U.S.C § 103(a), one of ordinary skill must justify eliminating arginine from the compositions disclosed. However, eliminating the primary component in a pharmacological composition is completely contrary to the conventional wisdom in the art. One of ordinary skill would not find it obvious to eliminate the disclosed primary active ingredient in a pharmacological composition and still reasonably expect it to function as described. Eliminating the primary active ingredient arginine from the compositions described in Babish as suggestion by the Office would render the disclosed compositions unsatisfactory for their intended purposes of treating CAD and hyperlipidemia. See MPEP § 2145 (if the proposed modification would render the prior art invention being modified unsatisfactory for its intended purpose, then it can not render the claims obvious).

Furthermore, Rath fails to provide any teaching or suggestion regarding the importance of coenzyme Q10 and cholecalciferol apart from the 35 other disclosed ingredients. The Office can not identify a reason why a person of ordinary skill in the art would take the composition of Rath, consisting of 37 active ingredients, and randomly choose two of the 37 ingredients (to the exclusion of the other 35) to add to the secondary components of the composition of Babish. Moreover, Rath teaches that the exact formulation consisting of the 37 disclosed ingredients is required for the

composition to function satisfactorily for its intended purpose. For example, all examples include all 37 ingredients. Claim 1 of Rath recites a composition "consisting of" all 37 ingredients. See MPEP § 2111.03 (the transition phrase "consisting of" excludes any ingredient not specified in the claim). Further, there are no instances in the disclosure of Rath where it is taught or suggested that any subset of the 37 disclosed ingredients is amenable to any use in exclusion of the other ingredients or that additional ingredients may be added to or substituted for any of the 37 disclosed ingredients.

Accordingly, Rath teaches away from arbitrarily selecting only coenzyme Q10 and cholecalciferol from the 35 other required ingredients. See MPEP § 2141.02 (prior art references must be considered in their entirety, i.e., as a whole, including portions that would lead away from the claimed invention). Therefore, given the teachings of Rath, one of ordinary skill in the art would not randomly select two nondescript ingredients, ignore 35 other equally important active ingredients, add the two nondescript ingredients to secondary ingredients from a different pharmacological composition, and expect that the resulting composition would function to treat a class of diseases completely different than the class of diseases the original compositions were intended to treat.

For reasons analogous to those described above, one of ordinary skill in the art would not add the fatty acid mixture of Gonzales-Bravo to secondary ingredients from a different pharmacological composition, and expect that the resulting composition would function to treat a class of diseases completely different than the class of diseases the

original compositions were intended to treat.

The Office can not establish the obviousness of the compositions for treating autoimmune diseases claimed in the present application by describing a miscellaneous amalgam of various ingredients randomly selected from references that teach particular compositions for treating CAD and hyperlipidemia - a completely unrelated class of diseases. Accordingly, claim 1 of the present application and its dependent claims (see MPEP § 2143.03) are not rendered obvious by the cited references because (i) they are nonanalogous art, and (ii) they do not teach or suggest to one of ordinary skill in the art the claimed compositions for treating autoimmune disease and immuno-inflammatory diseases. For reasons analogous to those stated above, claims 65 and 66 are not rendered obvious by the cited references.

CONCLUSION

In view of the above, Applicant respectfully requests withdrawal of the rejections and the issuance of a notice of allowance. Rejoinder of claim 6, drawn to withdrawn species, and consideration of the nonelected species are requested. If the undersigned can be of assistance to the Examiner in advancing the application to allowance, please contact the undersigned representative for Applicant at the number set forth below.

Respectfully submitted,

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